

## 510(k) Summary

<b>Date Submitted:</b>	July 30, 2009
<b>Manufacturer:</b>	Spine Smith Partners, LLC 93 Red River Austin, TX 78701
<b>Contact Name:</b>	Robert Jones
<b>Phone:</b>	512-302-0086
<b>Device Trade Name:</b>	Fusionary Graft Delivery System
<b>Common Name:</b>	Piston syringe
<b>Regulatory Class:</b>	880.5860
<b>Classification Code:</b>	Class II
<b>Product Code:</b>	FMF
<b>Predicate Devices:</b>	SmartPREP II/Graft Delivery System (Harvest Technologies, Inc.) GPSIII System (Biomet, Inc.) Bone Graft Syringe (Wright Medical Technology)
<b>Device Description:</b>	The Fusionary Bone Marrow Aspirate and Graft Delivery Kits include Jamshidi needles, syringes, the anti-coagulant ACD-A, a dual applicator manifold and various ancillary components.
<b>Intended Use:</b>	The Fusionary Bone Marrow Aspirate and Graft Delivery Kits are intended to be used to aspirate bone marrow, autologous blood, plasma, or other blood components. In addition, they are designed to facilitate pre-mixing of bone graft materials with aspirate, I.V. fluids, blood, plasma, platelet rich plasma or other specific blood component(s) as deemed necessary by the clinical use requirements.
<b>Substantial Equivalence:</b>	The intended use, materials and design features are substantially equivalent to the predicate systems used for bone marrow aspiration and graft delivery.